National Institute for Quality- and Organizational Development in Healthcare and Medicines

CERTIFICATE NUMBER: ***OGYI/50251-10/2012***

1 , 2

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended
Art. 15 of Directive 2001/20/EC

The competent authority of Hungary confirms the following:
The manufacturer: ***Izotóp Intézet Kft./Institute of Isotopes Co. Ltd.***
Site address: ***Konkoly Thege M. u. 29-33., Budapest, 1121, Hungary***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***OGYI/50251-8/2012*** in accordance with Art. 40 of Directive 2001/83/EC and Art. 13 of Directive 2001/20/EC .

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2013-01-15*** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The authorisation referred to in paragraph 40(1) of Directive 2001/83/EC and 44(1) of Directive 2001/82/EC, as amended, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database*

[3] *The Competent Authority is responsible for appropriate linking of the authorisation with the manufacturer's application (Art. 42(3) of Directive 2001/83/EC and Art. 46(3) of Directive 2001/82/EC as amended).*

Part 2

Human Medicinal Products Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids Special Requirements 5 Radiopharmaceuticals 1.1.1.6 Other: Other(en) Special Requirements 7 Other: Kits for radiolabelling(en)
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids Special Requirements 5 Radiopharmaceuticals 1.1.2.5 Other: Other(en) Special Requirements 7 Other: Kits for radiolabelling(en)
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell Special Requirements 5 Radiopharmaceuticals 1.2.1.10 Radionuclide generators
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.4 Other: Active Substances(en)
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility 1.6.2 Microbiological: non-sterility 1.6.3 Chemical/Physical

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.1 Microbiological: sterility 2.1.2 Microbiological: non-sterility 2.1.3 Chemical/Physical
2.2	**Batch certification of imported medicinal products**

	2.2.1 Sterile products 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised
	2.2.2 Non-sterile products

Clarifying remarks (for public users)

Certificate includes Manufacturing and Importation operations for human Investigational Medicinal Products.

2013-07-15

Name and signature of the authorised person of the Competent Authority of Hungary

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